

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comperative clinical evaluation of resin based pit and fissure sealant and self adhering flowable composite

Protocol summary

Study aim

Comparison of clinical performance of resin based pit and fissure sealant with self-adhesive flowable composite resin.

Design

A clinical trial with two simultaneous interventions on the same individuals, with parallel groups, with a sample size of 40 patients and two samples from each patient, double blinded without randomization method.

Settings and conduct

This project will be carried out in the pediatric department of Kerman Dental School by one pediatric dental resident. Prior to treatment, parents will be given explanations about the clinical procedure and treatment rationale. Follow-up evaluations are performed by the same researcher and, if necessary, by two other researchers, who will comment on clinical criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children aged 6 to 12 years old; absence of cl I, cl II and cl v caries lesions in permanent mandibular first molars; possibility of isolation with cotton roll; presence of fully erupted teeth; absence of oral habits such as clenching; bruxism and heavy occlusion in the studied teeth; absence of previous dental treatment on the mandibular permanent first molars; molars with deep pit and fissures susceptible to caries lesion in the future; no medical systemic problems interfering in the study and not taking any medication which affects the saliva flow. Exclusion criteria: inability to be properly isolated by the operator; uncooperative children; permanent mandibular first molars with dentin caries lesion; the presence of opaque-gray shadows on the bottom of the grooves and the presence of grooves and fissures with brownish-gray color branching from the center of the groove to the around of the groove or pit.

Intervention groups

Intervention No. 1: Flowable self-adhesive composite
Intervention No. 2: Resin based pit and fissure sealant

Main outcome variables

self-adhesive composite retention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180521039763N4**

Registration date: **2021-04-15, 1400/01/26**

Registration timing: **prospective**

Last update: **2021-04-15, 1400/01/26**

Update count: **0**

Registration date

2021-04-15, 1400/01/26

Registrant information

Name

Fatemeh Jahanimoghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comperative clinical evaluation of resin based pit and fissure sealant and self adhering flowable composite

Public title

Comperative clinical evaluation of resin based pit and fissure sealant and self adhering flowable composite

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged 6 to 12 years Permanent first molars of the mandible with no cl I, cl II and cl v caries lesion Possibility of isolation with cotton roll Fully erupted permanent molars Absence of oral habits such as clenching, bruxism and heavy occlusion in the studied teeth Absence of previous dental treatment on the first permanent mandibular molars Molars with deep pit and fissures with the susceptibility of future caries Absence of interfering medical systemic problems in the study Not consuming any drugs that affect saliva flow

Exclusion criteria:

Unablity of the operator for proper isolation Uncooperative child Permanent first mandibular molars with dentin caries lesions Existence of opaque-gray shadows on the bottom of the grooves Existence of grooves and fissures with brown-gray discoloration branching from the center of the groove to around of the groove or pit

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

For each patient, two permanent first mandibular molars will be considered. The 80 studied teeth will be divided into two groups of 40. All teeth were treated by the same operator. First, the surface of the teeth is cleaned of debris and plaque with a rotating brush, and after washing and drying the tooth surfaces and examining the occlusion with articulating paper, each tooth is isolated by a cotton roll inside the buccal and lingual vestibule. Then, the tooth surfaces of both groups are prepared for placement of two types of materials for pit and fissure sealant, so that in each patient, the first permanent lower molar tooth on the bottom right is sealed with self-adhesive flowable composite resin with (Vertise Flow with A2 color from Kerr company, USA) and the first permanent lower molar tooth on the left side is sealed with the light cure pit and fissure-sealant resin with A2 color (Master-Dent company from USA)

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in this clinical trial are not aware of the type of material used to treat each of their teeth, and the statistics consultant is not aware of the type of treatment performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman university of medical sciences

Street address

Kerman University of Medical Sciences, Shafa crossroad, Jomhuri Eslami Blvd.

City

Kerman

Province

Kerman

Postal code

7618759689

Approval date

2021-01-21, 1399/11/02

Ethics committee reference number

IR.KMU.REC.1399.556

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Self-adhesive composite retention and incidence of secondry caries

Timepoint

3, 6, 12 months

Method of measurement

Clinical examination with a dental probe and a dental mirror

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the surface of the first permanent lower right molar in each patient is cleaned of debris and plaque by a rotating brush, and after rinsing and drying the dental surfaces and examining the occlusion by articulating paper, it is isolated by a cotton roll inside the buccal lingual vestibule. Then, according to the manufacturer instructions of the self-adhesive flowable composite (Vertise flow) based on the no need for acid etching and bonding process before placing the composite, after drying the teeth, the self-adhesive composite (with maximum thickness of 0.5 mm) by using a microbrush is placed on the grooves of the teeth for 20 seconds and then cured for 40 seconds using a light curing device (Coltene AG, Altstätten, Coltolux Switzerland).

Category

Prevention

2

Description

Intervention group: First, the surface of the first permanent lower left molar in each patient was cleaned of debris and plaque with a rotating brush, and after washing and drying the tooth surfaces and examining the occlusion by articulator paper, it was isolated by a cotton roll inside the buccal and lingual vestibule. Then pits and fissures of the occlusal surfaces of the molar are etched with 37% phosphoric acid (Brasil / FGM) for 20 seconds and then rinsed with water for 15 seconds and dried by gentle air flow. If the etching surfaces are contaminated with saliva, the tooth surface will be etched again for 10 seconds. Then, two layers of Adper bonding are applied and a gentle stream of air is used for five seconds to evaporate the solvent, and then the curing is performed with a light curing device for 20 seconds, after that the resin-based pit and fissure sealant is placed on the bonding. After ensuring the absence of voids by gently moving the dental probe over the pit and fissures, the sealant is cured for 40 seconds.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman university of medical sciences, faculty of dentistry

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
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Full name of responsible person
Reyhane Aftabi
Position
Pediatric dentistry resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only a portion of the data is shared, such as the original outcome information

When the data will become available and for how long

Start the access period, 6 months after printing the results

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

For researchers

From where data/document is obtainable

reyhane9495@gmail.com

What processes are involved for a request to access data/document

1 month

Comments